

Proposed Regulation of Cosmetic Surgery Procedures

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) Cosmetic Surgical Facility.

(a) "Cosmetic surgical facility" means an office or a facility in which a cosmetic surgical procedure is performed.

(b) "Cosmetic surgical facility" does not include:

(i) An ambulatory surgical facility;

(ii) A hospital; or

(iii) An office owned or operated by one or more dentists providing services within the scope of practice of dentistry.

(2) Cosmetic Surgical Procedure.

(a) "Cosmetic surgical procedure" means the use of surgical services to reshape the structure of a human body to change the appearance of an individual.

(b) "Cosmetic surgical procedure" does not include:

(i) A procedure done under local anesthesia or mild sedation; or

(ii) Liposuction that removes less than 1,000 cubic centimeters of aspirate.

(3) "Department" means the Department of Health and Mental Hygiene.

(4) "Facility" means a cosmetic surgical facility as defined in §B(1) of this regulation.

(5) "Health care practitioner" means a person who is licensed, certified, or otherwise authorized under the Health Occupations Article, Annotated Code of Maryland, to provide health care services in the ordinary course of business or practice of a profession.

(6) "License" means a document issued by the Secretary to a person to operate a cosmetic surgical facility.

(7) "Licensee" means the person, association, partnership, or corporation to whom a license is issued.

(8) "Secretary" means the Secretary of Health and Mental Hygiene or the Secretary's designee.

.02 License Required.

A. A person may not establish or operate a cosmetic surgical facility without obtaining a license from the Secretary.

B. License Period and Fee.

(1) A license is valid for 3 years from the date of issuance, unless suspended or revoked by the Secretary.

(2) The applicant shall submit a nonrefundable fee of \$3,000 for a 3 year period, with an application for initial licensure, or submit a nonrefundable fee of \$3,000 with an application for license renewal for a 3 year period.

C. A license issued under this chapter is not transferable.

.03 Licensing Procedure.

A. A person desiring to operate a facility shall:

(1) Be in compliance with all applicable federal, State, and local laws and regulations;

(2) Be accredited as a cosmetic surgical facility by:

(a) The American Association for Accreditation of Ambulatory Surgical Facilities;

(b) The Accreditation Association for Ambulatory Health Care;

(c) The Joint Commission; or

(d) An accreditation organization approved by the Secretary;

(2) File an application on a form provided by the Department;

application for license renewal for a 3 year period; and

(3) Pay the licensure fee set forth in .02 of this chapter.

B. An officer of a corporation or association shall apply for a license on behalf of the entity. The owner shall apply on behalf of a sole proprietorship. An applicant shall submit

the names of the entity's board members, owners, and investors having at least 2 percent ownership.

C. An authorized individual of a government unit or agency shall apply for a license on behalf of the government unit or agency.

D. Based on information provided to the Department by the applicant and the Department's own investigation, the Secretary shall:

(1) Approve the application unconditionally if the applicant complies with all requirements of this chapter;

(2) Approve the application conditionally; or

(3) Deny the application if the applicant:

(a) Has been convicted of:

(i) A felony that relates to Medicaid or Medicare,

(ii) A crime involving moral turpitude; or

(b) Does not comply with the requirements of this chapter.

F. Denial of License for Prior Revocation or Consent to Surrender License. The Secretary may deny a license to:

(1) A corporate applicant if the corporate entity has an owner, director, or officer:

(a) Whose conduct caused the revocation of a prior license, or

(b) Who held the same or similar position in another corporate entity which had its license revoked;

(2) An individual applicant:

(a) Whose conduct caused the revocation of a prior license, or

(b) Who held a position as owner, director, or officer in a corporate entity which had its license revoked; or

(3) An individual or corporate applicant that has consented to surrender a license as a result of a license revocation action.

G. The Secretary shall also consider the factors identified in Regulation .10C of this chapter when deciding whether to deny a license.

H. A person aggrieved by a decision of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .12 of this chapter.

I. Renewal of License.

(1) At least 60 days before a license expires, the licensee shall submit a renewal application to the Secretary.

(2) The Secretary shall renew the license for an additional 3-year period for a licensee that meets the requirements of this chapter.

J. Provisional License. Licenses for Less than 3 Years. The Department may issue a provisional license if:

(1) A facility is not in full compliance with this chapter:

(a) But in the opinion of the Department, the noncompliance does not constitute a safety or health hazard; and

(b) The applicant or licensee has submitted a plan of correction acceptable to the Department which satisfactorily addresses the correction of each deficiency within a time frame acceptable to the Department; or

(2) Departmental administrative delays have occurred which:

(a) Are beyond the control of the applicant or licensee; and

(b) Have prevented the Department from completing its licensure activity.

E. Transfer or Assignment of License Prohibited. If the sale, transfer, assignment, or lease of a cosmetic surgical facility causes a change in the person or persons who control or operate the facility, the Department shall consider the facility to be a new facility and the licensee shall conform to all regulations applicable at the time of transfer of operations.

F. Return of License. The current license shall become void immediately and the licensee shall return the license to the Secretary if the facility:

(1) Is sold or leased;

(2) Ceases to operate;

(3) Moves to a new permanent location; or

(4) Has its license denied, suspended or revoked.

.04 Service Standards.

A. The licensee is responsible for compliance with all laws and regulations applicable to the operation of a cosmetic surgical center.

B. (1) The licensee shall meet the standards for the operation of a cosmetic surgical center issued by its accreditation organization.

(2) If a licensee loses its accreditation, the licensee shall immediately:

(a) Cease operations;

(b) Notify the Department; and

(c) Return the license certificate to the Department.

C. Regardless of its accreditation status, the licensee shall comply with all requirements set forth in this chapter.

D. The licensee is not required to comply with a higher standard than that required of an ambulatory surgical facility under Health-General Article, Title 19, Subtitle 3B and its implementing regulations.

.05 Investigation by the Secretary.

A. The Secretary may investigate complaints concerning the conformance of a cosmetic surgical facility to the requirements of this chapter and for compliance with the standards for the operation of a cosmetic surgical center issued by its accreditation organization.

B. A facility shall be open during normal business hours, or any other times that the facility is serving patients, for inspection by the Department and by any other agency designated by the Secretary to investigate complaints.

C. The Department shall refer complaints concerning a health care practitioner's performance or a health care practitioner's conformance to the standards of medical practice to the appropriate health occupations board that licenses, certifies, or otherwise regulates the health care practitioner under the Health Occupations Article, Maryland Annotated Code.

C. Noncompliance.

(1) If the Secretary determines that a licensee fails to meet any provision of this chapter or fails to comply with the standards for the operation of a cosmetic surgical center issued by its accreditation organization, the Secretary shall:

(a) Advise the licensee of the exact nature of the violation; and

(b) Require that the facility specify what corrective action it is taking and monitor the facility to ensure that it takes corrective action.

(2) This section does not preclude the Secretary from imposing any of the sanctions set forth in this chapter.

(3) The Secretary may not specify that a licensee correct a violation of a standard that is a higher standard than that required of an ambulatory surgical facility under Health-General Article, Title 19, Subtitle 3B and its implementing regulations.

D. Records and Reports. The facility shall make its records and reports available to the Department or its designee for inspection during the investigation of a complaint. On the written request of the Department, the facility shall immediately provide photocopies of records and reports, including clinical records of patients.

.06 Medical Records.

A. The facility shall maintain a complete, comprehensive, and accurate medical record for each patient.

B. Each patient's medical record shall include at least the following:

(1) Patient identifier;

(2) Significant medical history and results of a physical examination;

(3) Documentation of care or services provided;

(4) Evidence of consent; and

(5) Discharge diagnosis.

C. The facility shall:

(1) Send a copy of the medical record with the patient on referral to another health care provider or on transfer to a hospital;

(2) Use the medical record, if appropriate, in instructing the patient and the family; and

(3) Comply with all disclosure requirements as set forth in Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland.

.07 Patient's Rights.

- A. The administrator shall ensure that the facility develops and implements written policies and procedures concerning patients' rights and responsibilities.
- B. The facility shall make the policies and procedures available to patients, guardians, or other health care decision makers, as defined by Health-General Article, Title 5, Subtitle 6, Annotated Code of Maryland, and the public.
- C. The policies and procedures shall ensure that:
- (1) The facility informs patients of services that are available and the charges for services not covered by third-party payors;
 - (2) A physician, dentist, podiatrist, or other qualified health care practitioner informs patients of their medical conditions unless medically contraindicated as documented in their medical records;
 - (3) All patients are afforded an opportunity to participate in planning their medical treatments and to refuse to participate in experimental research; and
 - (4) All patients are ensured confidential treatment of their medical records, and may approve or refuse release of records to any individual outside the facility, except as provided by federal or State law.

.08 Physical Environment.

- A. The facility shall meet all federal, State, and local laws, ordinances, and regulations for construction.
- B. The facility shall meet all safety requirements of the National Fire Protection Association, NFPA 101 "Life Safety Code", which is incorporated by reference at COMAR 29.06.01.06.
- C. The facility shall meet the requirements for handling, treatment, and disposal of special medical wastes as provided in COMAR 10.06.06.

.09 Emergency Suspension.

- A. The Secretary may immediately suspend a license on a finding that the public health, safety, or welfare requires emergency action.
- B. The Department shall deliver a written notice to the licensee informing the licensee of the emergency suspension, giving the reasons for the action and the regulation or regulations with which the licensee has failed to comply that forms the basis for the emergency suspension, and notifying the licensee of the licensee's right to request a hearing and to be represented by counsel.

C. The filing of a hearing request does not stay the emergency action.

D. When a license is immediately suspended, the licensee shall:

(1) Immediately return the license to the Department; and

(2) Stop providing services immediately.

E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .11 of this chapter.

F. The Office on Administrative Hearings shall conduct a hearing as set forth in Regulation .09 of this chapter and issue a proposed decision within 10 business days of the close of the hearing record. Exceptions may be filed by an aggrieved person pursuant to COMAR 10.01.03. The Secretary shall make a final decision pursuant to COMAR 10.01.03.

G. If the Secretary's final decision does not uphold the emergency suspension, the licensee may resume operation.

.10 Revocation of License.

A. Revocation of License. The Secretary, for cause shown, shall notify the licensee of the Secretary's decision to revoke the facility's license. The revocation shall be stayed if a hearing is requested.

B. (1) The Secretary may revoke a license if the licensee:

(a) Has been convicted of a felony that relates to Medicaid or Medicare or a crime involving moral turpitude;

(b) Does not comply with the requirements of this chapter; or

(c) Fails to comply with the standards for the operation of a cosmetic surgical center issued by its accreditation organization.

(2) The Secretary may not revoke a license for a violation of a standard that is a higher standard than that required of an ambulatory surgical facility under Health-General Article, Title 19, Subtitle 3B and its implementing regulations.

C. The Secretary shall also consider the following factors when deciding whether to revoke a license:

(1) The number, nature, and seriousness of the violations;

(2) The extent to which the violation or violations are part of an ongoing pattern during the preceding 24 months;

(3) The degree of risk, caused by the violation or violations, to the health, life, or safety of the patients of the facility;

(4) The efforts made by, and the ability of, the licensee to correct the violation or violations in a timely manner; and

(5) Such other factors as justice may require.

D. The Secretary shall notify the licensee in writing of the following:

(1) The effective date of the revocation;

(2) The reason for the revocation;

(3) The regulations with which the licensee has failed to comply that form the basis for the revocation;

(4) That the licensee is entitled to a hearing if requested, and to be represented by counsel;

(5) That the facility shall stop providing services on the effective date of the revocation if the licensee does not request a hearing;

(6) That the revocation shall be stayed if a hearing is requested; and

(7) That the licensee is required to surrender the license to the Department if the revocation is upheld.

E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .12 of this chapter.

.11 Penalties.

A. Administrative Penalty. The Secretary may impose an administrative penalty of up to \$1,000 for a violation of any provision of this chapter.

B. When considering whether to impose an administrative penalty and the amount of the penalty, the Secretary shall consider the following factors:

(1) The number, nature, and seriousness of the violations;

(2) The extent to which the violation or violations are part of an ongoing pattern during the preceding 24 months;

(3) The degree of risk, caused by the violation or violations, to the health, life, or safety of the patients of the facility;

(4) The efforts made by, and the ability of, the licensee to correct the violation or violations in a timely manner; and

(5) Such other factors as justice may require.

E. A person aggrieved by the action of the Secretary under §A of this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .12 of this chapter.

.12 Hearings.

A. A request for a hearing shall be filed with the Office of Administrative Hearings, with a copy to the Office of Health Care Quality of the Department, not later than 30 days after receipt of notice of the Secretary's action. The request shall include a copy of the Secretary's action.

B. A hearing requested under this chapter shall be conducted in accordance with State Government Article, §10-201 et seq., Annotated Code of Maryland, and COMAR 28.02.01 and 10.01.03.

C. The burden of proof is as set forth in COMAR 10.01.03.28.

D. Unless otherwise stated in this chapter, the Office of Administrative Hearings shall issue a proposed decision within the time frames set forth in COMAR 28.02.01.

E. The aggrieved person may file exceptions as set forth in COMAR 10.01.03.35.

F. The Secretary shall issue a final decision in accordance with COMAR 10.01.03.35.